UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

SAB-EHC-87-029

May 11, 1987

OFFICE OF
THE ADMINISTRATOR

Honorable Lee M. Thomas
Administrator
U. S. Environmental Protection Agency
401 M Street, S. W.
Washington, D. C. 20460

Dear Mr. Thomas:

The Drinking Water Subcommittee of the Science Advisory Board's Environmental Health Committee has completed its review of the Drinking Water Criteria Document for Nitrate and Nitrite and is pleased to transmit its conclusions and recommendations to you.

The Subcommittee advises that further technical changes are warranted before finalizing the document. Specifically, the staff should clarify the use of the Walton study, including the limitations of the study and the weight assigned to its use for regulatory decision making. Second, a clearer scientific rationale should be presented on the selection of margins of safety. These and other issues are discussed in the attached report.

We appreciate the opportunity to conduct this scientific review and request a formal response to the Subcommittee's report.

Sincerely,

Richard Griesemer

Richard Griesemer, Chairman
Environmental Health Committee
Science Advisory Board

Norton Nelson

Norton Nelson, Chairman
Executive Committee
Science Advisory Board

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

May 11, 1987

Dr. Richard A. Griesemer
Chairman
Environmental Health Committee
Science Advisory Board
U. S. Environmental Protection Agency
401 M Street, S. W.
Washington, D. C. 20460

OFFICE OF
THE ADMINISTRATOR

Dear Dr. Griesemer:

The Drinking Water Subcommittee of the Environmental Health Committee has completed its review of the Office of Drinking Water Criteria Document for Nitrate and Nitrite. The Subcommittee concludes that the current document merits further revision before a final version is prepared for use as a technical basis for regulatory decision making. The two major reasons for the Subcommittee's finding are stated below.

First, the documentation and its presentation are incomplete and confusing, thus creating difficulties in reaching conclusions on matters of scientific interpretation. For example, the observations of Walton are used as a basis for determining acceptable levels for a ten-day health advisory. The Subcommittee is particularly concerned about the weight given the Walton study. The document describes the study in the summary with little or no interpretation of the underlying study design, but its importance merits an expert review by an epidemiologist. The study needs to be fully described in the body of the document along with conclusions as to its limitations and relative importance. Further, the same critical approach should be followed for all studies that are crucial to the development of proposed standards.

Second, public health standards setting involves the examination and selection of appropriate margins of safety. The Safe Drinking Water Act and its later Amendments specify that EPA address this issue. It is especially critical here since the document cites the National Academy of Sciences report (Drinking Water and Health, 1977) that remarks on the narrow margin of safety for nitrates. In the Criteria Document for Nitrate and Nitrite, the Agency selects a margin of safety that excludes, for all practical purposes, protection of sensitive members of the population, namely, infants with gastrointestinal disease. The staff should clarify its technical rationale for developing a margin of safety, as well as the need to include or exclude particular subgroups of the population, for example, those individuals who are genetically disposed to only slowly reduce the methemoglobin. The Office of Drinking Water should set a single public health standard for the contribution from both nitrate and nitrite.

In addition, the Subcommittee notes that the document limits the consideration of exposure to oral ingestion of drinking water. The document should attempt to place into perspective the contributions of drinking water to total human health exposure by age group (particularly the endogenous sources); at present, there is little opportunity to determine to what extent Agency actions for drinking water will provide overall public health protection. The Subcommittee recommends that the Office of Drinking Water also expand the chapter on alternate pathways and sources of exposure to provide a more comprehensive analysis of relative exposure, and that the section on the quantification of toxicological effects examine in detail the contribution of nitrate and nitrite in drinking water to the risk of disease in various populations. A data gap exists for reproductive and developmental effects that the document should cite.

The Subcommittee concludes that the Agency can appropriately set a proposed health advisory level on the basis of methemoglobin formation. In addition, there is a carcinogenic potential of these inorganic ions in chemical combination with naturally occurring substances. The Subcommittee recommends that the Office of Drinking Water present a conclusion on the current knowledge about the potential for impacts of nitrosated materials from nitrate and nitrite in drinking water. The Criteria Document may require further revision if new information arises about this subject. Specifically, it is desirable to consider the case of splenic sarcomas in male rats which appear to be related to compounds that produce methemoglobemia. The Subcommittee also recommends that the nitrosamine issue (endogenous formation) could warrant a separate EPA position paper as some nitrosamines are likely to be human carcinogens.

Finally, the Subcommittee wishes to address an issue that is applicable not only to this document but to criteria documents or risk assessments in general. If reproductive and developmental toxicity data are not available from either reliable human epidemiologic studies, from concretely relatable human experience, or from valid state-of-the-art animal studies, this fact itself must be stated. Furthermore, when developmental toxicity data are available from animal studies, then both the NOEL and the magnitude of the most likely margin of safety between that animal NOEL and probable human exposure needs to be stated. A second point is the relationship of the vulnerability of the conceptus and the mother to the agent. If the agent in question produces developmental toxicity only at, or very near to, maternally toxic dose levels in an animal study, this needs to be stated as does the more hazardous situation wherein an agent produces adverse effects on the conceptus in the absence of any maternal homeostatic effect.

Sincerely,

Gary Carlson, Chairman
Drinking Water Subcommittee

Robert Tardiff, Vice-Chairman
Drinking Water Subcommittee